

JUL 27 2001

**510K SUMMARY – Alliger Ultrasonic Surgical System Model AUSS-5**

K012028

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMSA 1990 and 21CFR 807.92.

**1. Submitter's Identification**

Name: MISONIX, INC.  
Address: 1938 New Highway, Farmingdale, NY 11735  
Telephone Number: (631) 694-9555  
Contact Person: Albert F. Clancy Jr.  
Date Prepared: 22 June 2001

**2. Name of Device**

Proprietary Name: Alliger Ultrasonic Surgical System Model AUSS-5  
  
Common / Usual Name: Ultrasonic Surgical System  
Ultrasonic Surgical Aspirator  
  
Classification Name: Instrument, Ultrasonic Surgical

**3. Predicate Device Information**

Predicate Devices Alliger Ultrasonic Surgical System model AUSS-4 and the Cavitron Ultrasonic Surgical Aspirator (CUSA) Model NS-100 Ultrasonic Surgical Aspirator

**4. Device Description** The Alliger Ultrasonic Surgical System is comprised of a generator, which feeds a 22.5 kHz electrical signal to a piezoelectric crystals mounted in a hand-held handpiece; the crystals then vibrate at the same frequency. The titanium tip attached to the handpiece amplifies the vibration. An irrigation / aspiration unit is provided to introduce irrigation solution and remove fragmented material and waste liquids from the area.

**5. Intended Use:** The Alliger Ultrasonic Surgical System is indicated for use in the fragmentation and aspiration of both soft and hard (e.g.: bone) tissue in the following surgical specialties:

Neurosurgery  
Gastrointestinal and Affiliated Organ Surgery  
Urological Surgery  
Plastic and Reconstructive Surgery  
General Surgery  
Orthopedic Surgery  
Gynecology  
    External genitalia  
    - condyloma  
    - benign tumors (lipomas, fibromas, and leiomyomas)  
    - malignant primary and metastatic tumors of all types  
    and the following cystic lesions:  
        - Bartholin's cysts  
        - Vestibular adenitis  
        - Inclusion cysts  
        - Sebaceous cysts

Abdominal area

any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus.

Thoracic Surgery

Limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies, and metastatectomies

6. Comparison to Predicate Device:

The Alliger Ultrasonic Surgical Systems are similar in design, material and operating parameters to the CUSA NS-100 Ultrasonic Surgical Aspirator. Although the CUSA NS-100 has a magneto-strictive transducer and the Alliger Ultrasonic Surgical Systems have a piezoelectric transducer, and has been previously determined by the FDA to be substantially equivalent.

7. Discussions of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Output Frequency Measurements  
Output Power Measurements (No Load to Maximum Load)  
Tip Displacement Measurements  
Irrigation Flowrate Measurements (Ultrasound On and Flush Mode)  
Life Tests  
Vacuum Flowrate and Pressure Measurements  
Input Power Measurements  
EMI Tests  
Dielectric Tests on Mains Circuits  
Patient Current Leakage and Patient Sink Current Measurements  
Power Line Ground Leakage Measurements  
Dielectric Tests on Patient Circuits.

8. Discussions of Clinical Tests Performed

N/A

9. Conclusions

Based upon an analysis of the operating characteristic specifications, Output of Engineering Tests, Hazard Analysis, and Voluntary Consensus Standard Investigations, Misonix, Inc. has concluded that the Alliger Ultrasonic Surgical System Model AUSS-5 is substantially equivalent to both the AUSS-4, and the CUSA Model NS-100 system.



JUL 27 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Albert F. Clancy, Jr.  
Manager, Quality Assurance/Regulatory Affairs  
Misonix, Inc.  
1938 New Highway  
Farmingdale, New York 11735

Re: K012028

Trade/Device Name: Alliger Ultrasonic Surgical System (Model AUSS-5)  
Regulation Number: 878.4400  
Regulatory Class: II  
Product Code: LFL  
Dated: June 22, 2001  
Received: June 28, 2001

Dear Mr. Clancy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

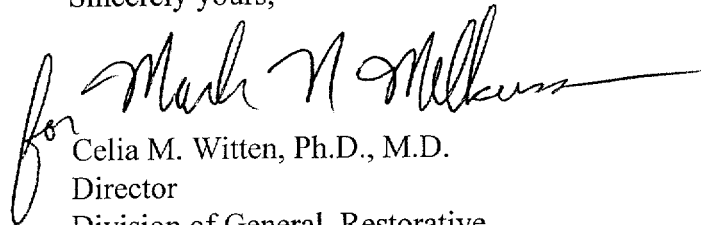
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive, flowing style.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## PREMARKET NOTIFICATION

### INDICATIONS FOR USE

510k Number: K012028

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Gastrointestinal and Affiliated Organ Surgery  
Urological Surgery  
Plastic and Reconstructive Surgery  
General Surgery  
Orthopedic Surgery  
Gynecology

#### External genitalia

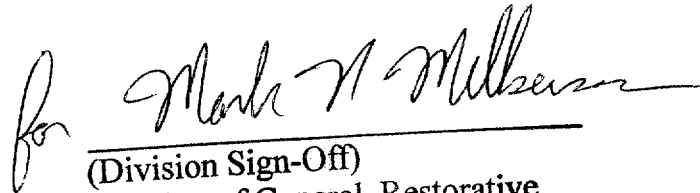
- condyloma
- benign tumors (lipomas, fibromas, and leiomyomas)
- malignant primary and metastatic tumors of all types and the following cystic lesions:
  - Bartholin's cysts
  - Vestibular adenitis
  - Inclusion cysts
  - Sebaceous cysts

#### Abdominal area

- Any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus.

Thoracic Surgery

- Limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies, and metastatectomies

for 

(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number

K012028